

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

**IN RE: GENERIC PHARMACEUTICALS
PRICING ANTITRUST LITIGATION**

**MDL 2724
16-MD-2724**

THIS DOCUMENT RELATES TO:

HON. CYNTHIA M. RUFÉ

ALL ACTIONS

MEMORANDUM OPINION

Rufe, J.

November 14, 2019

On October 24, 2019, the Court entered a Case Management Order as Pretrial Order No. 105 (“PTO 105” or “CMO”), substantially approving the Report and Recommended Order of Special Master David Marion and setting an initial schedule for discovery, class certification, summary judgment, and *Daubert* motions applicable to all cases pending in the Multi-District Litigation as of September 1, 2019. Moving Defendants objected to certain provisions of the CMO and have filed a motion in this Court to stay discovery while they seek a writ of mandamus from the Court of Appeals to argue that the CMO does not comply with the Federal Rules of Civil Procedure. Plaintiffs oppose the stay. Because the provisions of the CMO are appropriate in the context of this exceedingly large and complex antitrust MDL, the motion for a stay will be denied.

I. Procedural Background of the MDL

This MDL concerns allegations that numerous pharmaceutical companies engaged in an unlawful scheme or schemes to fix, maintain, and stabilize prices, rig bids, and engage in market and customer allocations of certain generic pharmaceutical products. There are five distinct sets of Plaintiffs: The State Attorneys General, three proposed class-action Plaintiff groups (the Direct Purchaser Plaintiffs (“DPPs”), the End-Payer Plaintiffs (“EPPs”), and the Indirect Reseller

Plaintiffs (“IRPs”)), and the Direct Action Plaintiffs, who have opted not to proceed as part of one of the class actions. More than two dozen corporations and individuals have been named as Defendants. The MDL initially involved allegations of individual conspiracies as to 18 separate generic drugs, but has expanded to encompass allegations of overarching conspiracies that include dozens of pharmaceuticals. The Court has ruled on numerous motions to dismiss, and has determined that federal and state claims can proceed both as to individual drugs¹ and as to the alleged existence of an overarching multi-drug conspiracy in separate complaints brought by the Plaintiff groups.²

A particular challenge in this MDL has been the need to balance the conduct of discovery in an orderly, proportional fashion in accordance with the Federal Rules of Civil Procedure with due regard for the investigations conducted by the State Attorneys General and the United States Department of Justice, which is an Intervenor in the MDL. Discovery thus has proceeded in gradual, targeted stages.³

In recognition of the scope of the MDL, the Court has appointed three highly-qualified Special Masters to assist the Court and to work with the parties to resolve disputes informally, where possible, and to provide the Court with recommendations when agreement cannot be reached. Special Master Marion, Special Discovery Master Bruce Merenstein, and a specialist in electronically stored information, Special Discovery Master for ESI Daniel Regard, have many years of experience in cases with complex discovery.

¹ Specifically, the Court denied motions to dismiss (except as to one Defendant), the Sherman Act claims asserted by the DPPs, EPPs, and IRPs and the state-law claims asserted by the EPPs and the IRPS as to six individual drugs, clobetasol, digoxin, divalproex ER, doxycycline, econazole, and pravastatin (the “Group One” drugs). *See* MDL Doc. Nos. 857, 858 (entered October 16, 2018) and MDL Doc. Nos. 721, 722 (entered February 15, 2019).

² MDL Doc. Nos. 1070, 1071 (entered August 19, 2019).

³ *See* PTO 44 [MDL Doc. No. 560, entered February 9, 2018]; PTO 47 [MDL Doc. No. 582, entered April 19, 2018]; PTO 60 [MDL Doc. No. 774, entered November 20, 2018]; PTO 73 [MDL Doc. No. 853, entered February 14, 2019]; PTO 96 [MDL Doc. No. 1046, entered July 12, 2019]; PTO 108 [MDL Doc. No. 1151, entered November 8, 2019].

The Court has entered orders designed to protect the parties' interests with regard to sensitive information. PTO 45⁴ set forth the procedure for designating information as confidential or highly confidential and also set forth a separate category of non-privileged material generated or disclosed in connection with investigations by State Attorneys General. As different needs for protecting information were identified, PTO 45 was modified by PTO 53, to permit highly competitive or highly sensitive information likely to have a significant effect on business strategies or decisions, product plans or development, or pricing to be designated for "outside counsel eyes only."⁵

Before and after filing suit, several State Attorneys General, and in particular the Connecticut State Attorney General, conducted investigations pursuant to state law. The other Plaintiff groups sought access to the material obtained through such investigations, and by Order dated November 14, 2018⁶, the Court explained at length why such access was warranted as long as there were procedures to protect confidentiality and comply with Connecticut state law. As a result of this Order, and under the auspices of Special Master Marion, the parties agreed to a stipulated protocol implementing the Court's Order, which the Court entered as PTO 70.⁷ PTO 70 provided for a "claw back" procedure, whereby:

if Defendants believe the procedures outlined [in PTO 70 and protective orders] are insufficient to protect (a) competitively sensitive or trade secret information; (b) business information unrelated to allegations in any MDL pleading; or (c) personal or embarrassing information unrelated to any allegation in the MDL, Defendants can submit an objection to Plaintiffs seeking to "claw back" such documents. Absent good cause (including for such issues as document volume), objections will be made within 30 days after the provision of access to a Defendant's documents. Objections shall identify the documents at issue, together

⁴ [MDL Doc. No. 561, entered February 13, 2018].

⁵ [MDL Doc. No. 697, entered September 4, 2018], at ¶ 1.7.

⁶ [MDL Doc. No. 758].

⁷ [MDL Doc. No. 841, entered January 31, 2019]. PTO 70 has been modified with the agreement of the parties, but this provision was not affected. *See* PTO 106 [MDL Doc. No. 1142, entered October 25, 2019].

with the grounds for objection. If Plaintiffs disagree with such an objection, it will be considered by the Special Master. Defendants may not seek to claw back documents based on grounds other than those described above or as set forth in PTO 53 pertaining to inadvertent production of privileged material.⁸

II. The CMO is Consistent with the Federal Rules of Civil Procedure and the Court's Earlier Orders

The protections established in PTO 70, as just explained, have been expressly incorporated into the CMO, including Paragraph 3, to which Defendants particularly object. Paragraph 3 of PTO 105 governs the production of custodial files, and provides that search terms for the files shall be established, after which

Defendants shall apply the agreed search terms to the agreed custodial files and may review the identified documents for privilege, but may not withhold prior to production any documents based on relevance or responsiveness.⁹

Defendants contend that they should be permitted to withhold documents they determine to be irrelevant or nonresponsive before production.

The agreed custodial files are defined in the ESI Protocol as the files of “any individual of a Producing Party as identified and agreed by the parties during a meet and confer as having possession, custody, or control of potentially relevant information, Documents, or ESI.”¹⁰ Thus, there is no dispute that these custodial files are likely to contain relevant information. Importantly, the agreed custodial files are not produced wholesale; instead, the files are to be searched for specific terms. These search terms provide the initial screen for relevance. Once the information has been produced it is not irretrievable; the “claw back” procedures established in PTO 70 for confidential information are expressly incorporated into the CMO: documents are stamped “Outside Counsel Eyes Only” for 120 days, with requests to claw back made within 120 days of

⁸ PTO 70, ¶¶6-7.

⁹ CMO ¶ 3(b).

¹⁰ PTO 95 at ¶ 1.5.

production.¹¹ Claw back disputes are to be “resolved promptly with assistance from Special Discovery Master Merenstein and Special Master Marion, as necessary.”¹²

The procedures outlined above establish a path forward fully commensurate with Federal Rule of Civil Procedure 26, which provides that

Parties may obtain discovery of nonprivileged matter that is relevant to any party’s claim or defense and proportional to the needs of the case, considering the importance of the issues at stake in the action, the amount in controversy, the parties’ relative access to relevant information, the parties’ resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit.¹³

There is no question that the issues at stake in this action are of considerable importance to the parties, to the shareholders of those Defendants that are publicly-traded corporations, and to the public at large. The agreed custodial files are by their terms those likely to have relevant information, the files will be searched for specific relevant terms, and Defendants have the opportunity to claw back confidential information. In the context of this litigation, where the relevance of the documents must be determined in part by context, these procedures best serve the purpose of the Federal Rules to secure a just determination of the merits of the parties’ claims and defenses.

The CMO also comports with the earlier rulings of the Court with regard to the search for and production of discovery material (the “ESI Protocol”).¹⁴ The parties thoroughly briefed and argued several disputed issues before the ESI Protocol was entered. The highly technical disputes were resolved with the benefit of a recommendation from Special Discovery Master for ESI Regard. The Court separately ruled on a disputed legal question, holding that a party may redact or

¹¹ CMO ¶ 3(e).

¹² CMO ¶ 3(e).

¹³ Fed. R. Civ. P. 26(b).

¹⁴ See PTO 95 [MDL Doc. No. 1045, entered July 12, 2019].

withhold responsive documents only when covered by attorney-client privilege or the work-product doctrine or when the documents contain sensitive personally identifying information.¹⁵ As the Court explained, “the particular nature of the antitrust allegations in the MDL mean that an understanding of the context of particular documents may be critical, which could be impeded by the withholding or redaction of responsive documents or document families.”¹⁶ The CMO thus does not depart from, but instead forms the latest chapter in, the Court’s comprehensive management of the MDL.

III. A Stay Is Not Warranted

The factors in determining whether to grant a stay are:

(1) whether the stay applicant has made a strong showing that he is likely to succeed on the merits; (2) whether the applicant will be irreparably injured absent a stay; (3) whether issuance of the stay will substantially injure the other parties interested in the proceeding; and (4) where the public interest lies.¹⁷

For the reasons discussed above, Moving Defendants have not made a strong showing of likelihood of success on the merits. The CMO was not issued in a vacuum. Instead, as the intricate procedural history of this complex MDL illustrates, the CMO is the latest in a series of rulings designed to advance discovery with due consideration of the ongoing federal and state investigations and the parties’ legitimate interests. The Court understands the burdens that large volumes of discovery place on the parties, but Defendants have not shown that reviewing information for relevance before production, instead of through the claw back procedures established in PTO 70 and incorporated in the CMO, is appropriate in this litigation, where the

¹⁵ Order on Proposed ESI Protocol [MDL Doc. No. 938, entered April 10, 2019].

¹⁶ *Id.* at 1. The Court also cited the protective order, and the parties’ ability to raise appropriate objections to discovery, which the Special Masters may assist the Court in resolving. *Id.* at 1-2.

¹⁷ *Republic of Philippines v. Westinghouse Elec. Corp.*, 949 F.2d 653, 658 (3d Cir. 1991) (citing *Hilton v. Braunskill*, 481 U.S. 770, 777 (1987)).

determination of whether information is potentially relevant requires the context of the information within the files. Nor have Defendants shown that they would be irreparably injured in the absence of a stay. To the contrary, the complexity of the MDL, and the balancing of interests of all concerned, has resulted in a deliberate, gradual expansion of discovery, and now that the groundwork has been laid, a stay would work against the interests of the parties and run counter to the public interest.

Now the MDL has been brought to the stage where comprehensive discovery is proceeding, Moving Defendants attempt to halt the progress the Court has made and disrupt the pace and the content of the administration of the MDL, issues within the sound discretion of the Court, by invoking the extraordinary remedy of mandamus. There is no basis for such an action. The question of whether there has been a widespread conspiracy to artificially inflate the cost of many generic pharmaceuticals is an issue that directly affects many Americans, and it is time for discovery to show whether or not that has occurred. The Court determined that Plaintiffs have plausibly alleged an overarching antitrust conspiracy; now Plaintiffs must marshal evidence to prove their claims and Defendants must prepare their defenses, and the CMO provides a reasonable way forward for all parties.

During the past three years, the Court has entered orders that balance the competing interests at stake in an ever-evolving and complex MDL. The Court maintains a detailed awareness of these developments and acts with the benefit of input received through regular status conferences with counsel, through reports of the Special Masters, and through extensive motions practice, and makes rulings based upon all of this acquired knowledge. As discovery expands, the Court will continue to ensure that the discovery process proceeds in an orderly, proportional fashion that is reasonably calculated to lead to the discovery of relevant information. The Court therefore will not stay proceedings. An appropriate order will be entered.